

REMARKS/ARGUMENTS

The examiner is thanked for clarifying the remaining issues.

In response to the enablement rejection, claims 1 and 2 (and claims dependent therefrom) have been amended to specify the definition of SERMs set forth at page 10, lines 13-17 of the specification. The SERMs defined by the claims are all believed to have predictable physiological effects on the estrogen receptors of different tissues, and this commonality of mechanism among the claimed SERMs provides the predictability that is required for enablement (i.e. an expectation that each class member will perform the desired function in the context of the claimed invention. Likewise, estrogens and androgens have entirely predictable effects on the estrogen and androgen receptors, respectively.

Accordingly, it is urged that the enablement rejections should be withdrawn.

In response to both obviousness rejections, it is pointed out that each relies on EM-652.HCl being provided by reference WO 96/26201. However, the '201 reference teaches that EM-652.HCl is an estrogen receptor antagonist -- i.e. a compound that would have been expected to block the estrogen receptors so that the estrogen of the invention would have been unable to desirably activate those receptors in tissues that respond favorably to estrogen receptor activation. Applicants' present specification teaches that such antagonistic activity does not occur, but there is no suggestion of that in the cited '201 reference. It is the cited prior art -- not applicants' specification -- that must suggest the invention if an obviousness rejection is to be upheld.

According to MPEP 706.02(J), 35 U.S.C. 103 authorizes a rejection where, to meet the claim, it is necessary to modify a single reference or to combine it with one or more other references. After indicating that the rejection is under 35 U.S.C. 103, the examiner should set forth in the Office Action:

- (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column of page number(s) and line number(s) where appropriate,
- (B) the difference or differences in the claim over the applied reference(s),
- (C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and
- (D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 - §2143.03 for decisions pertinent to each of these criteria.

Because the motivation to make the combination is in applicants' specification and not in the cited prior art, it is urged that the obviousness rejections should be withdrawn.

In response to the double patenting rejections, it is pointed out that both such rejections rely upon references claiming the combination of SERM and precursors (e.g. DHEA). The examiner correctly points out that the present rejected claims may add DHEA. However, even when DHEA is added to the presently-claimed combinations, DHEA is in addition to estrogen --not in lieu of estrogen. Stated differently, DHEA is an optional third agent whereas estrogen is required whether DHEA is present or not. It is the claims' requirement of estrogen that is not suggested by the cited references' provision of DHEA. Accordingly, it is urged that the double patenting rejections be withdrawn.

It is urged that the application is now in condition for allowance. Issuance of a notice of allowance is solicited.

EXPRESS MAIL CERTIFICATE

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail to Addressee (mail label # EV606188115US) in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 30, 2006:

William O. Gray, III

Name of Person Mailing Correspondence

Signature
May 30, 2006

Date of Signature

WOG:db

Respectfully submitted,

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